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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Reto Lerf et al.	) Group Art Unit 3738
Appl. No.	:	10/519,338	)
Filed	:	September 19, 2005	)
For	:	OPEN-PORED METAL COATING FOR JOINT REPLACEMENT IMPLANTS AND METHOD FOR PRODUCTION THEREOF	)
Examiner	:	YARNALL, MEGAN LEIGH	)

DECLARATION OF VINZENZ MAX FRAUCHIGER PURSUANT TO 37 C.F.R. § 1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, Dr. Vinzenz M. Frauchiger, do declare as follows:

1. I am a citizen of Switzerland and currently reside at Hans Roth-Strasse 7b, CH-4500 Solothurn, Switzerland.

2. I am currently a Project Manager in the research department of Smith & Nephew Orthopaedics AG, Aarau, Switzerland. I lead and coordinate research projects in the field of medical implant surfaces

3. I hold a Doctorate in Materials Science of Biomaterials Surface, from the Federal Institute of Technology, Zurich, Switzerland.

4. I have been involved in over 10 research projects over the past 10 years in the area of biomedical materials research, including the research and development of implant surfaces in contact with hard and soft tissue.

5. I have written 11 publications and been an inventor on 2 patents and 3 patent applications relating to biomedical implants.

6. Dr. Hans Schmotzer and Dr. Reto Lerf are the inventors in the above-identified application. I am the current project manager responsible for the above-identified application. I have reviewed the Office Action issued in the above-identified application on December 9, 2008 and the claims as amended in the Office Action response filed with this declaration. I have also reviewed U.S. Patent Nos. 3,855,638 ("Pilliar"); 5,034,186 ("Shimamune"); 5,456,723 ("Steinemann"); 4,542,539 ("Rowe"); and 4,206,516 ("Pilliar2"), and U.S. Patent Application No. 2004/0030387 ("Landry"), the references identified by the Office Action to reject the claims of the application under 35 U.S.C. § 103(a).

7. In my opinion, Pilliar and Steinemann, as well as the other references relied upon by the Office Action in rejecting the claims under 35 U.S.C. § 103(a), do not render obvious the claimed invention for the following reasons:

8. Neither Pilliar nor Steinemann, alone or in combination, teaches or even suggests an open-pored surface layer further comprising a surface micro-structure in the sub-micrometer range, much less where the open-pored surface layer comprises particles sized in a range of approximately 50 µm to 800 µm, as recited by certain pending claims of the above-identified application. Such a combination of features provides unexpected results in comparison to the prior art and would not have been apparent to one of ordinary skill in the art at the time of the invention.

9. For almost 20 years two contradictory ideas developed independently, pursuing the same goal: to improve bonding and long-term hold between an artificial implant surface and bone tissue. The side of the literature promoting large open-pores is embodied by Pilliar, Shimamune, and Rowe. The other side of the literature, promoting a small roughening, is embodied by Steinemann. Both of these distinct solution strategies have met some success independently. However, absent a deeper understanding of each method's underlying mechanisms, one of ordinary skill had no motivation to combine the two nor a reasonable expectation of success of achieving the claimed invention by combining the teachings of Pilliar and Steinemann. Instead, each school of thought taught against the other. Steinemann clarifies this distinction's prevalence in the prior art at col. 6 lines 29-33, where Steinemann notes that its

prescription "stands in perfect contrast to opinions expressed so far in literature. According to these opinions an optimum bond between bone and implant requires a contact surface roughness of more then 20 µm." Steinemann did not consider combining the two distinct techniques, but instead viewed them as contradictory.

10. Pilliar embodies the aforementioned first school of thought, promoting large open-pores. As described in Pilliar: "it is <u>essential</u> that the interstitial pore size exceed about 50 microns." Pilliar at col. 3 lines 52-54 (emphasis added).

11. As realized by the Applicants, the open pores and submicron roughness provide completely different mechanisms for binding bone with the implant surface. Such larger pore sizes are necessary to allow bone tissue to grow into the implant surface through the pores (e.g., in-growth), which creates a stronger interlocking mechanical connection between the bone and the implant, making it unnecessary for the bone to physically bond with the implant surface. Smaller surface features, such as those discussed in Steinemann, would not provide sufficient space for such in-growth. Further, non-open features such as the sand-blasted pits of Steinemann would not provide the same functionality, as these pits do not allow as strong a connection as the porous structures taught, e.g., in Pilliar. Shimamune, Rowe, and Pilliar2 embody the same principles as Pilliar, promoting bone in-growth through generally large open pores.

12. Steinemann embodies the aforementioned second school of thought, promoting a small roughening. As described in Steinemann: "a porous contact surface on a metallic implant is able to... [make] the mating bone intergrow with the implant along the contact surface and speedily form a strong and durable bond, provided that the contact surface displays a micro-roughness with pits of the order of magnitude of 2 µm or less." Steinemann at col. 3 lines 19-24.

13. As realized by the Applicants, such smaller roughening allows bone cells to grow onto (e.g., on-growth) and adhere to the surface on a microscopic scale. The large pores of Pilliar are too big for such cellular adhesion. Further, the processes described by Pilliar smooth the surface, removing any potentially preexisting microstructure called for in Steinemann.

14. Notably, Steinemann specifically addressed the large-pore techniques of Pilliar, but did not consider the combination now proposed in the Office Action. Instead, Steinemann distinguished the large pore technique, as discussed above. Moreover, an attempt to combine the features from Pilliar and Steinemann, would not work. Steinemann describes a strong etch of the

surface with a reducing acid (Steinemann at col. 5 lines 19-27); an etching process strong enough to severely damage, and to a degree destroy, the surface of Pilliar. Accordingly, a combination of Steinemann with Pilliar would essentially result in a surface resembling that of Steinemann alone, as the etching process therein described would significantly damage the surface of Pilliar. This would also be the case should the technique of Steinemann be combined with the teachings of either Shimamune or Rowe. Generally, the use of such an etch would dramatically attack and damage any surface similar to those described in any of Pilliar, Shimamune or Rowe, irrespective of whether this was plasma spray deposited or sintered. The strength of the etch of Steinemann also significantly reduces desirable mechanical properties such as fatigue and abrasion resistance. This would drastically affect the mechanical integrity of each of the coatings defined in Pilliar, Shimamune or Rowe, to such an extent that they might be rendered unusable as medical implants. Essentially the particles held within the surface layer prior to the Steinemann etch would become too loosely bound, and there would be a significant risk of particle release into the body after implant. This would simply be too much of a safety risk to allow their use. Additionally, Pilliar and the other large-pore implants rely on such mechanical properties to maintain connection with the bone. Accordingly, a combination of Steinemann with Pilliar to provide an open-pored surface layer with a surface micro-structure in the sub-micrometer range would be inoperable.

15. As discussed above, the combination of Steinemann and Pilliar would not enable production of open-pored implant surface with particle sizes in a range of approximately 50 μm to 800 μm with an additional surface micro-structure. In the present invention the acid etch can be controlled to produce fine etching pits without the problems discussed above that result from the strong etching process in Steinemann. Such controlled etching to maintain larger pores was generally not considered viable for implant-bone bonding prior to this application, as evidenced at least by Steinemann's Examples II, IV, and V, which use a less aggressive etching technique and are rejected by Steinemann. Accordingly, the combination of Pilliar with Steinemann certainly does not render obvious producing a surface micro-structure in a controlled manner to preserve the open-pored structure to allow ingrowth of bone, as recited in claims 45, 46.

16. Combining Steinemann with a plasma-treated surface in general would not have been considered appropriate prior to the subject application. Steinemann describes plasma

sprayed layers as having tendencies to break or peel from the implant surface. Accordingly, Steinemann was aware of such techniques, but opted not to use them in combination with the acid etch. Instead, Steinemann notes the superiority of its method over plasma coats at col. 6 lines 24-27. Nowhere does Steinemann suggest combining these techniques. Indeed, as described above, these techniques were viewed as contradictory at the time of the invention. Accordingly, Steinemann alone or in combination with the other references cited does not teach a method of producing an open-pored coated implant comprising both particles with size in a range of approximately 50 μm to 800 μm and a surface micro-structure on the open-pored surface, at least one of the open-pored implant surface and the surface micro-structure being produced by a vacuum plasma spraying method, as recited, for example, in claims 9, 33 and 37.

17. I declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the above-identified application and any patents issuing thereon.

Dated: April 2, 2009

V. Frauchiger
Vinzenz M. Frauchiger

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